



EURORDIS
Rare Diseases Europe

EUROPEAN REFERENCE NETWORKS OF CENTRES OF EXPERTISE

A European Reference Network of Centres of Expertise (ERN) is the physical or virtual networking of knowledge and expertise of national Centres of Expertise (CoE) in more than one European country. The goal of a ERN is the improvement in the overall quality and management of care of a single rare disease (RD) or a group of RDs with similar health care needs by complementing, supporting and providing added-value to the existing services and expertise at the national level. Such networking activity between national CoE promotes the sharing and mobility of expertise rather than patients themselves, but permits the travelling of patients to cross-border CoE when necessary. Patients in every European country can benefit from a ERN, although CoE that are members of the network are not necessary in every European country.



WHY ARE EUROPEAN REFERENCE NETWORKS REQUIRED?

The Communication from the Commission, “Rare Diseases: Europe’s Challenges”¹ proposes that Member States put in place strategies organised around “ensuring access to high-quality healthcare, in particular through identifying national and regional CoE and foster their participation in ERN”.

The Commission’s Council Recommendation² on Action in the Field of Rare Diseases accompanying this communication recommends that Member States:

- Foster the participation of CoE in ERN respecting the national competences and rules with regard to their authorisation or recognition.
- Organise healthcare pathways for patients suffering from RDs through the establishment of cooperation with relevant experts and exchange of professionals and expertise within the country or from abroad when necessary.
- Support the use of information and communication technologies such as telemedicine where it is necessary to ensure distant access to the specific healthcare needed.
- Include, in their plans or strategies, the necessary conditions for the diffusion and mobility of expertise and knowledge in order to facilitate the treatment of patients in their proximity.

The European Project for Rare Diseases National Plans Development (EUROPLAN) recommendations³ underscore the importance of Member States to identify national or regional CoE and encourage their participation in ERN.

Article 15 of the proposal of Directive of the European Parliament and of the Council on the application of patients’ rights in cross-border healthcare⁴ provides for the development of ERN to be facilitated by the Member States.

WHY ARE EUROPEAN REFERENCE NETWORKS IMPORTANT TO RARE DISEASE PATIENTS?

Due to the large number of RD, to their low individual prevalence, their severity, and to the scarcity of the information about each of them, the field of RD is one in which benefits of collaboration of expertise and maximisation of limited resources are most obvious, especially for ultra RDs in which expertise may only be available in a very small number of European countries. As a CoE cannot exist for each RD in each European country, patients may sometimes need to receive care across borders. The added-value of ERN was put forth by several existing multilateral cross border health care agreements, many European Commission funded projects, documented by the European Commission High Level Group on Medical Care and Health Services , and may be demonstrated more recently by the currently funded EC pilot projects.

1 COM(2008)679 Communication from the Commission to the European Parliament, the Council the Economic and Social Committee and the Committee of the Regions on Rare Diseases: Europe’s challenges.
2 Council Recommendation of 8 June 2009 on an action in the field of rare diseases.
3 -Draft recommendations for the development of strategic plan for rare diseases including methodological guidance. 28 October, 2009. Final recommendations available on the EUROPLAN website, www.europlanproject.eu
4 - (COM(2008)414) Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients’ rights in cross-border healthcare

HOW TO ADDRESS THE ISSUE?

• Scope of Activities

By creating a network of experts in national and regional CoE, ERN should:

- Improve knowledge of RD by sharing and creating mutual data-bases of information, organising trainings for patients and health professionals, and exchanging resources.
- Establish registries, databases, biobanks
- Increase cohorts for research studies and clinical trials
- Produce standards of diagnosis and care and social best practice protocols
- Support the creation and development of patient or patient organisation networks
- Bridge the gap between healthcare professionals and patients by involving patients in the governing, work, and evaluation of ERN
- Bring together experts from a group of disorders with similar medical and social needs
- Contribute to the improvement of services provided at national CoE via benchmarking
- Provide patient's access to a multidisciplinary team of experts and support the provision of cross-border care when no national CoE exists
- Provide patient's access to a multidisciplinary team of experts and provide appropriate arrangements for patient referrals from other CoE

• Designation

Several options have been proposed⁶ for a procedure for the identification and development of ERN by a European monitoring body composed of experts from relevant medical specialties, patients and their representatives, representatives of member states, health authorities, and the European Commission. Designation criteria⁷ should be consistently developed across RDs and will evolve with experience, time, and evolution of needs.

• Evaluation

Although a ERN should fulfil designation criteria, the comparative relevance of those various criteria will depend on the particular disease or group of diseases covered. CoE that are members of a ERN should meet designation criteria outlined in the EURORDIS Policy Factsheet on Centres of Expertise. Continued compliance with designation criteria should be ensured through external evaluation (the European Commission and relevant national authorities) and internal evaluation (by ERN members, in particular patient representatives) via standardised evaluation tools. This will remerge progressively in coming years.

• Long-term Sustainable Funding

Sustainability of ERN is a major issue. Long-term and sustainable funding of networks is crucial to their success as the common tools they establish (e.g. registries, biobanks, etc.) often take longer than is currently allotted in classic funding schemes to build, implement, and most importantly, use. The future Directive on cross border health care and patient mobility should provide a legal and financial instrument for the long-term identification, implementation, and development of ERN.

Examples of ERN pilot projects funded by the European Union's Health Programme:

- European Centres of Reference Network for Cystic Fibrosis (www.ecorn-cf.eu)
- A European Network of Centres of Expertise for Dysmorphology (www.dyscerne.org)
- Improving Health Care and Social Support for Patients and Family affected by Severe Genodermatoses (www.tag-eu.org)
- A Reference Network for Langerhans Cell Histiocytosis and Associated Syndromes (www.eurohistio.net)

RELATED ISSUES

- Due to the varying definition of RDs in Europe, differing health-care structures, different definitions of a CoE and differences among the diseases in question, a ERN consisting of individual CoE will also reflect this variability.
- The political commitment of Member States to identify and financially support CoE is a prerequisite for the creation of ERN. As MS are primarily responsible for organisation, financing and delivery of healthcare some political willingness to defer national autonomy will be necessary in the pursuit of pan-European equity.
- The existence of a ERN for each RD is unrealistic. ERN that address groups of RD may contribute to the solution of this problem.
- Inclusion of some CoE but not others in the ERN may introduce a lack of trust of local services.
- Pan-European networking activities between CoE often exist that do not strictly follow the recommended criteria of a ERN.
- Evaluation of CoE should be consistent, but a European-wide evaluation system may infringe on the principle of subsidiarity in Member States.
- Creating ERN may generate disproportionate bureaucracy for accreditation and evaluation mechanisms.
- Although hierarchy of CoE making up a network is discouraged, experts from one CoE will have to coordinate activities. There is a risk that hierarchy will nevertheless be introduced.
- It will always be difficult to determine whether improvements in morbidity and mortality of patients are due to the involvement of a CoE in a ERN or due to other factors.

REFERENCES AND ADDITIONAL INFORMATION

- EURORDIS. Policy Fact Sheet on Centres of Expertise. www.eurordis.org
- EURORDIS. EURORDIS Specific Contribution to the Public Consultation: «Rare Diseases: Europe's Challenges» regarding Centres of Expertise. <http://www.eurordis.org/IMG/pdf/position-paper-EURORDIS-centres-excellence-networksFeb08.pdf>
- EURORDIS. European Workshop on Centres of Expertise and Reference Networks for Rare Diseases Report. Rare Disease Solidarity Project (RAPSODY). http://www.eurordis.org/IMG/pdf/EU_workshop_report_3.pdf
- European Commission Directorate General of Health and Consumers. European Networks of Reference for Rare Diseases. http://ec.europa.eu/health/ph_threats/non_com/rare_8_en.htm#2
- European Commission. Work of the High Level Group on Health Services and Medical Care during 2005. http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2005_013_en.pdf
- European Commission. Work of the High Level Group on Health Services and Medical Care during 2006 http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2006_007_en.pdf
- European Commission. Options for a Procedure for Identification and Development of European Reference Networks http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2006_007_a1_en.pdf
- Rare Disease Task Force. European Reference Networks in the Field of Rare Diseases: State of the Art and Future Directions. <http://www.orpha.net/testor/cgi-bin/OTmain.php?&UserCell=workingGroup>

5 - Report from the High Level Group to the Employment, Social Affairs, Health and Consumer Protection Council on 6-7 December 2004 (HLG/2004/21 FINAL)

6 - See "Options for a Procedure for Identification and Development of European Reference Networks", in ADDITIONAL REFERENCES.

7 - See "Work of the High Level Group on Health Services and Medical Care during 2006", in ADDITIONAL REFERENCES